OCT 2 3 2003

K023723

510(k) SUMMARY

FMS FINOMETER NONINVASIVE HEMODYNAMIC MONITOR

This 510(k) summary is being submitted in accordance with the requirements of SMDA and 21 CFR § 807.92

I. NAME OF SUBMITTER

FMS, Finapres Medical Systems BV
Simon Stevinweg 48
NL-6827 BT Arnhem
The Netherlands

Phone Number: +31 26 384 9080

Contact Person:
Gerard J. Langewouters, PhD.
General Manager FMS

U. S Agent for FMS
Richard Meissel
Propel Biomedical Consulting
15500 Rockfield Boulevard, Suite A-1
Irvine, CA 92618
Phone Number: 949-768-0444
Fax Number: 949-768-8400

Date Prepared: 10/30/02

II. DEVICE NAME AND CLASSIFICATION

Proprietary Name:	Finometer Noninvasive Hemodynamic Monitor
Common or Usual Name(s):	Noninvasive Blood Pressure Monitor Hemodynamic Monitor
Classification:	Class 1I
	CFR 870.1130, Product Code DXN, Noninvasive Blood Pressure Measurement System
	CFR 870.2770, Product Code DSB, Impedance Plethysmograph

III. PREDICATE DEVICES

The Finometer is substantially equivalent in design (methodology) and indications for use to the following devices that have been or still are in commercial distribution:

- Ohmeda 2300 Finapres© Blood Pressure Monitor, Ohmeda Medical, Englewood, CO 80112-5810, K822055
- Ohmeda 2350 Finapres® Blood Pressure Monitor, Ohmeda Medical, Englewood, CO 80112-5810, K880572
- Task Force Monitor 3040, CNSystems Medizintechnik GMBH, Europe, AU, K014063

The Finometer and Finapres are substantially equivalent in design, methodology, software, manufacture, materials, intended use and principle of operation. The Finometer, the Finapres, and the Task Force Monitor devices are intended for use for continuous monitoring of finger arterial blood pressure. Finometer, Finapres and Task Force Monitor are all stationary models. FMS considers the use of the Finometer-to be substantially equivalent to its predicate devices, the Ohmeda 2300 and 2350 Finapres and the CNSystems Task Force Monitor.

IV. DESCRIPTION

The Finometer Noninvasive Hemodynamic Monitor is a stationary device to record continuous noninvasive arterial blood pressure as well as additional hemodynamic parameters.

The Finometer is a stationary device. It consists of the Main Control Unit with electronics and a solid-state disk for storage. The Main Control Unit also contains the two pressurized air circuits, including air pumps, for the measurements using the Finapres methodology and for the RTF calibration methodology. A Frontend Unit is used to provide an interface for the electronic signals from the Main Control Unit electronics and air supply to the forger cuffs, an arm cuff, and an analog input/output unit. The Frontend Unit connects the Main Control Unit to the forger cuff, which in turn consists of an inflatable air bladder and an infrared photoplethysmograph

The Main Control Unit microprocessor has an internal solid-state disk storing up to 24 hours of continuous blood pressure and derived hemodynamic data. The Main Control Unit is equipped with an RS232 serial interface to transfer the data stored in the Finometer disk to a PC and to allow remote control of the Finometer.

The analog input/output unit provides four analog signal outputs for connection to other data acquisition systems, and provides three analog signal inputs for sampling and storing of external signals simultaneously with the Finometer data. An external (intra-arterial) blood pressure signal can be used to replace the finger blood pressure. The Finometer then will use the external pressure signal to derive all parameters.

BeatScope PC-software is also delivered with the Finometer to enable downloading, viewing, and further handling of Finometer data. BeatScope provides the capability of on-line monitoring, storage, and limited control of a Finometer measurement on a remote PC.

V. INTENDED USE

The Finometer is intended to be used when there is a need for a noninvasive hemodynamic monitor. The Finometer provides a noninvasive characterization of the arterial circulation and its beat-to-beat variability in pressure and flow as well as in various hemodynamic parameters derived from these pressure and flow signals. The device does not report any diagnosis but provides numerical values. It is the physician's responsibility to make proper judgments based on these numbers.

The noninvasively blood pressure waveform is measured by using the Finapres method of Penaz/Wesseling. Hemodynamic parameters include cardiac output and total peripheral resistance based on the Modelflow method of Wesseling.

The Finometer is intended to be installed and operated by a qualified physician or operator. Pressure measurements are validated for subjects above 18 years of age. The only mode of measuring blood pressure accurately is when the device is used with the return-to-flow method of calibration, if the pressure data are to comply with the recommendations of the AAMI SP10 standard.

Modelflow built-in calibration is useful from 18 years on. Cardiac output measured with this device under the Modelflow model requires a calibration with thermal dilution.

The physiological parameters provided by the device have clinical significance only if determined by a physician and should not be used as the sole means for a patient's diagnosis.

The data provided by the device can be further processed by the included PC-based BeatScope software.

VI. TECHNOLOGICAL CHARACTERISTICS

No new technology, materials, or change in efficacy have been introduced by FMS in the manufacture of the FMS Finometer Noninvasive Hemodynamic Monitor. The design, form, and materials of the monitor are equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 3 2003

Finapres Medical Systems BV
c/o Gerard J. Langewouters, Ph.D.
General Manager FMS
Simon Stevinweg 48
NL-6827 BT Arnhem
The Netherlands

Re: K023723
Trade Name: Finometer Noninvasive Hemodynamic Monitor, Model 1
Regulation Number: 21 CFR 870.1130 and 870.2770
Regulation Name: Noninvasive Blood Pressure Measurement System and Impedance Plethysmograph
Regulatory Class: Class II (two)
Product Code: DXN and DSB
Dated: August 8, 2003
Received: August 11, 2003

Dear Dr. Langewouters:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K023723

1/1

Include the following "Indications For Use" page that contains the applicant's name, name of the device and the intended use of the device. The information, data and labeling claims in the entire the 510(k) submission must support and agree with the "indications for use" statement.
*For a new submission, do NOT fill in the 510(k) number blank.

INDICATIONS FOR USE

Applicant: FMS, Finapres Medical Systems BV

510(k) Number (if known): N/A*

Device Name: Finometer Non-Invasive Hemodynamic Monitor

Indications For Use:

The Finometer is intended to be used when there is a need for a noninvasive hemodynamic monitor. The Finometer provides a noninvasive characterization of the arterial circulation and its beat-to-beat variability in pressure and flow as well as in various hemodynamic parameters derived from these pressure and flow signals. The device does not report any diagnosis but provides numerical values. It is the physician's responsibility to make proper judgments based on these numbers.

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The physiological parameters provided by the device have clinical significance only if determined by a physician and should not be used as the sole means for a patient's diagnosis.

The data provided by the device can be further processed by the included PC-based BeatScope software.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter ____
Per 21 CFR 801.109

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K023723